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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,787	06/18/2002	Peter Neubauer	10806-193	9630

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,787

Applicant(s)

NEUBAUER ET AL.

Examiner

Sheridan K Snedden

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/2/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Applicant's amendment of claims 1-9 and addition of new claims 10-20 filed 12 March 2002 is acknowledged. Claims 1-20 are pending.

Priority

2. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 5, 8, 9, 12-13, 18-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "short" in claim 1 is a relative term which renders the claim indefinite. The term "short" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 4, 10-11 recite a "phase of the cycle" which meaning is unclear. Furthermore, there is insufficient antecedent basis for this limitation in the claim as the phase of the cycle is not defined or recited in the claims.

Art Unit: 1653

Claims 5 and 12-13 recite the limitation "only during certain segments of the process." There is insufficient antecedent basis for this limitation in the claim as the segments of the process is not defined or recited in the claims.

Claims 8, 18-20 recite the limitation "depending of the promoter used." There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "recombinant product." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 5-8, 14, 16, 18, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kerns *et al.* (IDS ac). Kerns *et al.* describe a fermentation process that increases the yield of recombinant protein where the carbon/energy source is increased by oscillation. Kerns *et al.* alter the dosage rate and show improvement compared to continuous substrate addition (claims 2, 5). A feedback parameter controls the addition of the energy source (claim 6, 14). Lactose is used as the energy source (claim 7-8, 16, 18). Thus, the reference clearly anticipates the invention as recited in the claims.

Art Unit: 1653

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki *et al.* (JP 56-26592, see translation or Abstract). Suzuki *et al.* describe a fermentation process for denitrify waste water where the carbon/energy source is increased by oscillation. The applicant is reminded that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitation are able to stand alone. See *In re Hirao*, 535, F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Thus, the reference clearly anticipates the invention as recited in the claims.

7. Claim 1-7, 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Caston *et al.* (US 6,680,181). Caston *et al.* teach a method for the production of recombinant peptide by fed-batch cultivation of a microorganism in a bioreactor containing a medium comprising organic carbon source, nitrogen source and mineral salts, wherein the cultivation is carried out by the addition of the organic carbon source in oscillation feed, without exhaustion of the organic carbon source during the oscillation period, wherein the oscillation has a wave period of from about 1 to about 30 minutes. Preferably the organic carbon source is glucose. Thus, the reference clearly anticipates the invention as recited in the claims.

8. Claims 1-7, 10-17 are rejected under 35 U.S.C. 102(a) as anticipated by Nakamura *et al.* (US Patent 5,912,113). Nakamura *et al.* disclose a method of culturing

Art Unit: 1653

microorganisms in a batch culture, under aerobic environment whereby glucose is added to the culture media in an oscillating manner. As seen in the abstract as well as at column 10, the time between which glucose is added to the culture media can be less than 2 minutes as well as less than or equal to 30 minutes, thus changing the dosage rate. Thus, the reference clearly anticipates the invention as recited in the claims.

Conclusion

9. No claims are allowed.

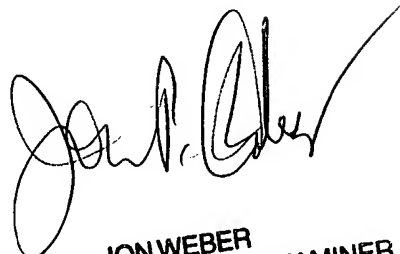
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K. Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
August 27, 2004

SKS


JON WEBER
SUPERVISORY PATENT EXAMINER